

Edgar Filing: ELAN CORP PLC - Form 6-K

ELAN CORP PLC  
Form 6-K  
March 31, 2005

FORM 6-K

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Report of Foreign Private Issuer  
Pursuant to Rule 13a-16 or 15d-16  
under the Securities Exchange Act of 1934

For the month of March, 2005

Commission File Number 001-13896

Elan Corporation, plc  
(Translation of registrant's name into English)

Treasury Building, Lower Grand Street, Dublin 2, Ireland  
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F    /X/                      Form 40-F    / /

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (1):

Yes    / /                                  No    /X/

Note: Regulation S-T Rule 101(b) (1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b) (7):

Yes    / /                                  No /X/

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Note: Regulation S-T Rule 101(b) (7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other

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Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes     /     /                                 No     /X/

If "Yes" is marked, indicate below the file number assigned to the registrant in connection with Rule 12g3-2(b):

This Report of Foreign Issuer on Form 6-K is incorporated by reference into the Post-Effective Amendments on Forms F-3 and S-8 to Form F-4 Registration Statement of Elan Corporation, plc (Registration No. 333-12756), the Registration Statement on Form F-3 of Elan Corporation, plc and Athena Neuroscience Finance, LLC (Registration No. 333-13130), and the Registration Statements on Form S-8 of Elan Corporation, plc (Registration Nos. 333-13996, 333-12344, 333-11940, 333-09644, 333-09284, 333-09048, 333-08384, 333-07361, 333-07136, 333-14240, 33-27506 and 333-100252).

### EXHIBIT LIST

| Exhibit | Description  |
|---------|--|
| 99.1    | Press release dated March 30, 2005 titled:<br>Elan and Biogen Idec announce TYSABRI(R) update. |

### SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ELAN CORPORATION, plc

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By: /s/ William F. Daniel

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William F. Daniel  
Company Secretary

Date: March 31, 2005

Exhibit 99.1

For More Information Contact:

MEDIA CONTACTS:

Biogen Idec: Jose Juves  
Ph: 617 914 6524

Elan: Anita Kawatra or Brian McGlynn  
Ph: 212 407 5740 or 800 252 3526

INVESTOR CONTACTS:

Biogen Idec: Elizabeth Woo  
Ph: 617 679 2812

Elan: Emer Reynolds  
Ph: 353 1 709 4000800 252 3526

ELAN AND BIOGEN IDEC ANNOUNCE TYSABRI(R) UPDATE

Dublin, Ireland and Cambridge, MA - March 30, 2005 - Elan Corporation, plc (NYSE: ELN) and Biogen Idec (NASDAQ: BIIB) announced today that their ongoing safety evaluation of TYSABRI(R) (natalizumab) has led to a previously diagnosed case of malignant astrocytoma being reassessed as progressive multifocal leukoencephalopathy (PML), in a patient in an open label Crohn's disease clinical trial.

In light of the two previously reported cases of PML in multiple sclerosis clinical trials, Elan and Biogen Idec initiated an additional comprehensive safety evaluation of TYSABRI clinical trial patients. In the course of this safety review, the companies identified a case warranting reassessment in an open label Crohn's disease clinical trial. In July 2003, the case was reported by a clinical trial investigator as malignant astrocytoma. This diagnosis was confirmed at the time by histopathology. The patient died in December 2003.

As part of this ongoing safety review, the companies, in agreement with the clinical trial investigator, reassessed the case. Following this additional evaluation, the diagnosis is being reassessed as PML. The patient had received 8 doses of TYSABRI over an 18 month period and prior medication history included multiple courses of immunosuppressant agents.

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Elan and Biogen Idec's comprehensive safety evaluation concerning TYSABRI and any possible link to PML is ongoing. The companies are reviewing clinical trial data, working with investigators to evaluate the approximately 3,000 patients in multiple sclerosis, Crohn's disease, and rheumatoid arthritis trials, and working with PML and neurology experts. The results of this safety evaluation will be discussed with regulatory agencies to determine possible re-initiation of dosing in clinical trials and future commercial availability.

On February 28, 2005, the companies announced that they had suspended marketing of TYSABRI in multiple sclerosis and dosing in all clinical trials based on two previously reported cases of PML, a rare and frequently fatal, demyelinating disease of the central nervous system.

### About Elan

Elan Corporation, plc is a neuroscience-based biotechnology company. We are committed to making a difference in the lives of patients and their families by dedicating ourselves to bringing innovations in science to fill significant unmet medical needs that continue to exist around the world. Elan shares trade on the New York, London and Dublin Stock Exchanges. For additional information about the company, please visit <http://www.elan.com>.

### About Biogen Idec

Biogen Idec creates new standards of care in oncology and immunology. As a global leader in the development, manufacturing, and commercialization of novel therapies, Biogen Idec transforms scientific discoveries into advances in human healthcare. For product labeling, press releases and additional information about the company, please visit <http://www.biogenidec.com>.

### Safe Harbor/Forward Looking Statements

This press release contains forward-looking statements regarding the potential for TYSABRI. These statements are based on the companies' current beliefs and expectations, and are subject to risks and uncertainties that could cause actual results to differ materially. There is no assurance, for example, that the serious adverse events discussed above were not caused by TYSABRI, that there are not or will not be more such serious adverse events or that we will be able to gain sufficient information to fully understand the risks associated with the product. There is also no assurance that the companies will be able to resume marketing and sales of TYSABRI. For more detailed information on the risks and uncertainties associated with TYSABRI and the companies' drug development and other activities, see the periodic and other reports of Biogen Idec Inc. and Elan Corporation, plc filed with the Securities and Exchange Commission. The companies assume no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.